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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,936	11/22/2005	Alain Loiseau	REGIM 3.3-058	8647

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EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/537,936	LOISEAU ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8 and 25* is/are allowed.

6)☒ Claim(s) *9-24 and 26-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 16-21, 23, 34-39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claims 16 and 34 are drawn to a method of regulating inflammatory mechanism. No specific disease or condition to be treated has been set forth.

Claims 17 and 35 are directed to treating an autoimmune disease, chronic inflammatory disease, atopic inflammatory disease and/or bowel disease.

Claims 18 and 36 are directed to a method of treating psoriasis, vitiligo, pityriasis, scleroderma, bullous dermatoses, eczema, atopic dermatitis, allergy and/or rheumatoid arthritis.

Claims 19 and 37 are directed to a method of treating chronic inflammation associated with aging.

Claims 20 and 38 are directed to a method of preventing and/or treating anaphylactic sensitization, pigmentary anomaly of the skin, dermal hypervascularization and/or inflammatory fissuring.

Claims 21 and 39 are directed to a method of regulating dermal tissue homeostasis.

Claims 23 and 41 are directed to a method of preventing aging of the skin, delaying natural aging of the skin, preventing accelerated aging of the skin, or preventing photo-induced aging of the skin .

(B) The state of the prior art.

The extract of Centella asiatica is known to be useful in wound treatment (Kim et al, U.S. Patent No. 6,417,349, column 1, lines 1-25).

(C) The level of predictability in the art.

The data in the specification presents in vitro data showing the effect of the claimed composition on a number of cytokines. On page 78 of the specification it stated that given the important role of these cytokines in the inflammatory process can be considered an element that is very favorable to the desired anti-inflammatory activity. However, there is no known correlation between the ability to modulate the production of cytokines and the treatment or prevention of any specific inflammatory disease or condition. Note that there are a large number of inflammatory conditions of different underlying causes and a person having ordinary skill in the art at the time the claimed invention was mad would not have been to predict based on the data provided in the specification for the treatment or prevention of which specific disease or condition the claimed methods would be useful.

(D) The amount of direction provided by the inventor.

The inventor provides a general statement on page 78 of the specification that the ability of claimed active agents to modulate various cytokines can be considered to be an element that is very favorable to the desired "anti-inflammatory" activity.

(E) The existence of working examples.

The examples in the specification are directed to the effect of the claimed active agents on modulation of various cytokines.

(F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Since there is no way to predict priori what effect the claimed drug would have on a large number of various inflammatory conditions encompassed by the present, it would take an enormous amount of experimentation to determine the effectiveness of the claimed methods against all the diseases and conditions encompassed by the present claims.

Claims 10 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 9 for the term "maderassoside" in claim 10.

It is not clear what is meant by the terminology "weight ration of madecassiside to madecassoside" (claim 24).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-15, 22, 24, 26-33 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sahu et al (Phytochemistry, vol. 28, no. 10, pp. 2852-2854, 1989).

Sahu et al disclose a mixture of two components madecassoside and terminoloside (pages 2852 and 2854). The claimed composition is anticipated by Sahu et al. In addition, if there is a difference in the amount of the components present in the composition, such difference would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been

prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention.

Claims 11-14, 22, 26, 27, 28, 31 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al (U.S. Patent No. 6,417,349).

The claimed extract of Centella asiatica contains a mixture of asiaticoside, madecassoside and terminoloside. Kim et al disclose an extract of Centella asiatica containing asiaticoside and madecassoside (column 2, lines 1-34). However, since terminoloside is structurally related to madecassoside, it would be expected to be inherently present in the reference's extract in the same or similar amount as encompassed by the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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GROUP 1200